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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,885	04/13/2004	George R. Krsek	KONEC 04.02	5661

7590 11/30/2006

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,885	KRSEK ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I in the reply filed on 11/10/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-6 are being examined on their merits herein, and claims 7-18 are being withdrawn from consideration as they do not read on the elected group. The restriction requirement is deemed proper and made **FINAL**.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kao et al. (U.S. PG-Pub 2003/0004177) in view of Mayer et al. (U.S. Patent 5,869,498).

Kao et al. teach pharmaceutical tablets containing opioid agonists, such as oxycodone (paragraph 0008 and 0018), in a matrix and an opioid antagonist in a separate matrix. The tablet is formulated as a controlled release in an effort to stop abuse of opioid agonists. It is taught that the two compositions are kept in separate matrixes, thus meeting the limitation of a bi-layer tablet in claim 1 (paragraph 0019).

The tablets of the invention include microcrystalline cellulose and magnesium stearate (meeting the limitation of claim 6; Examples 1 and 2).

Kao et al. does not teach a composition comprised of oxycodone and dextromethorphan, or a composition that does not include an opioid antagonist.

Mayer et al. teaches drug combinations of analgesics, including oxycodone, and NMDA receptor antagonists (including dextromethorphan; Col. 3, line 56 and Col. 4, line 30). Mayer et al. teaches compounds that do not include opioid antagonists.

Furthermore, it is obvious to vary and/or optimize the amount of oxycodone and dextromethorphan provided in the composition, according to the guidance provided by Mayer et al., to provide a composition having the desired properties such as the desired concentrations and ratios of active agents to produce the maximal analgesic effect. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kao et al., which teach bi-layer tablets comprised of opioid agonists and antagonists with the composition of Mayer et al., which teach pharmaceutical compositions comprised of oxycodone and dextromethorphan. Although Kao et al. teach a bi-layered tablet comprised of an opioid analgesic and an opioid antagonist (not claimed in the present invention), this reference is being used to teach that another drug can be added in a tablet with an opioid analgesic that will be beneficial in deterring abuse and dependence. One would have

been motivated to employ the concept of formulating a bi-layered tablet comprised of oxycodone and dextromethorphan in the present composition by the teachings of Mayer et al. which teach that NMDA receptor antagonists enhance the efficacy of opioid analgesics permitting a reduction in the amount of analgesic needed, and further inhibiting the development of dependence.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Kao et al. (U.S. PG-Pub 2003/0004177) in view of Mayer et al. (U.S. Patent 5,869,498) as applied to claims 1, 3-4 and 6 above, and in further view of Magruder et al. (U.S. Patent 4,851,229).

The teachings of Kao et al. and Mayer et al. are discussed in the 35 USC 103 rejection above.

Kao et al. and Mayer et al. do not teach an aperture portion, the dosage of the active ingredients or polyvinylpyrrolidone.

Magruder et al. teach osmotic delivery systems that contain a passageway to connect the interior and exterior portion of the tablet (meeting the limitation of claim 2; Col. 9, lines 48-52 and Figures 5 and 6). The system further contains a polyvinylpyrollidone (meeting the limitation of claim 5; Exampe 5).

Accordingly it would be obvious to one having ordinary skill in the art at the time of the invention to incorporate the teachings of Magruder et al., which teaches a passageway connecting the two portions of the tablet and a polyvinylpyrollidone with Kao et al and Mayer et al. One would be motivated to combine the teachings in order to

obtain a controlled release system that delivers drug at a controlled rate and at a controlled concentration.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER